

| | | | |
|-------------------------------|------------------------|---------------------|--|
| Notice of Allowability | Application No. | Applicant(s) | |
| | 10/591,403 | FUSHIMI ET AL. | |
| | Examiner | Art Unit | |
| | Jonathan S. Lau | 1623 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 18 Jun 2009.

2. ☒ The allowed claim(s) is/are 1,3,5-10,12,13 and 15-20.

3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.

(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached

1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.

(b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

| | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____ 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 5. <input type="checkbox"/> Notice of Informal Patent Application 6. <input type="checkbox"/> Interview Summary (PTO-413), Paper No./Mail Date _____ 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other _____ |
|---|--|

| | |
|--|--|
| | /Shaojia Anna Jiang/ Supervisory Patent Examiner, Art Unit 1623 |
|--|--|

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Peter Olexy on 5 Nov 2009.

The application has been amended as follows:

Amendment to the Claims

- Claims 25-29 are canceled.
- 17 (amended). A method for the inhibition of postprandial hyperglycemia, which comprises administering an effective amount of a fused heterocyclic derivative as claimed in claim 1, or a pharmaceutically acceptable salt thereof, ~~or a prodrug thereof.~~
- 18 (amended). A method for the ~~prevention or~~ treatment of a disease associated with hyperglycemia, which comprises administering an effective amount of a fused heterocyclic derivative as claimed in claim 1, or a pharmaceutically acceptable salt thereof, or a prodrug thereof..
- 19 (amended). A method for the ~~prevention or~~ treatment as claimed in claim 18, wherein the disease associated with hyperglycemia is a disease selected from the group consisting of diabetes, impaired glucose tolerance, diabetic complications, obesity, hyperinsulinemia,

Art Unit: 1623

hyperlipidemia, ~~hypercholesterolemia~~, hypertriglyceridemia, lipid metabolism disorder, atherosclerosis, hypertension, ~~congestive heart failure~~, and edema, ~~hyperuricemia and gout~~.

- 20 (amended). A method for the inhibition of advancing impaired glucose tolerance into diabetes in a subject, which comprises administering an effective amount of a fused heterocyclic derivative as claimed in claim 1, or a pharmaceutically acceptable salt thereof, ~~or a prodrug thereof~~.

DETAILED ACTION

This Office Action is responsive to Applicant's Amendment and Remarks, filed 18 Jun 2009, in which claims 1, 3, 5-9, 12 and 13 are amended to change the scope and breadth of the claim and claims 11 and 14 are canceled.

This application is the national stage entry of PCT/JP05/04152, filed 03 Mar 2005; and claims benefit of foreign priority document JAPAN 2004-61429, filed 04 Mar 2004; currently an English language translation of this foreign priority document is of record.

Claims 1, 3, 5-10, 12, 13, 15-20 are pending in the current application. Claims 17-20, previously withdrawn, are rejoined herein. Claims 25-29 are canceled by Examiner's Amendment, authorization for this examiner's amendment was given in a telephone interview with Peter Olexy on 5 Nov 2009.

Election/Restrictions

Claims 1, 3, 5-10, 12, 13, 15 and 16 are directed to an allowable product. Pursuant to the procedures set forth in MPEP § 821.04(b), claims 17-20, directed to the process of making or using the allowable product, previously withdrawn from consideration as a result of a restriction requirement, are hereby rejoined and fully examined for patentability under 37 CFR 1.104. Claims 25-29, directed to the invention(s) of Groups III and IV, do not all require all the limitations of an allowable

Art Unit: 1623

product claim, and have NOT been rejoined. Claims 25-29 are canceled by Examiner's Amendment, authorization for this examiner's amendment was given in a telephone interview with Peter Olexy on 5 Nov 2009.

Because a claimed invention previously withdrawn from consideration under 37 CFR 1.142 has been rejoined, **the restriction requirement between groups I and II as set forth in the Office action mailed on 3 Jan 2008 is hereby withdrawn.** In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Reasons for Allowance

Rejections Withdrawn

Applicant's Amendment, filed 18 Jun 2009, with respect to claims 1, 3 and 5-16 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement has been fully considered and is persuasive, as amended claims 1, 3, 5-9 do not recite a prodrug thereof, and claims 11 and 14 are canceled.

This rejection has been **withdrawn**.

Applicant's Amendment, filed 18 Jun 2009, with respect to claims 1, 3 and 5-16 are rejected under 35 U.S.C. 112, first paragraph as not being enabled for the full scope of the claim has been fully considered and is persuasive, as amended claims 1, 3, 5-9, 12 and 13 do not recite prevention of a disease associated with hyperglycemia or treatment of a disease associated with hyperglycemia selected from the group consisting of hypercholesterolemia, congestive heart failure, hyperuricemia and gout, and claims 11 and 14 are canceled.

This rejection has been **withdrawn**.

The following is an examiner's statement of reasons for allowance: The closest prior art is Ellsworth et al. (US Patent 6,414,126, issued 02 Jul 2002, of record) in view of Bedell et al. (J. Org. Chem., 1962, 27, p2026-2031, of record) and further in view of Shell (US Patent 5,582,837, issued 10 Dec 1996, of record).

Ellsworth et al. in view of Bedell et al. and further in view of Shell teaches as detailed in the Office Action mailed 27 Feb 2008.

Applicant's remarks, filed 27 Aug 2008, that Ellsworth et al. in view of Bedell et al. and further in view of Shell does not provide sufficient guidance to a person of ordinary skill in the art to arrive at the presently claimed invention wherein the glycoside is attached to the 5-membered ring of the fused heterocycle according to the presently claimed invention with a reasonable expectation of success is found to be persuasive. As noted by Applicant Ellsworth et al. provides guidance for the sugar moiety attached

Art Unit: 1623

at a position on the 6-membered benzene ring. Even if a specific fused heterocyclic ring, such as a benzothiophene ring, is selected from the broad genus taught by Ellsworth et al. it would not have been obvious to one of ordinary skill in the art to select the specific position on a specific fused heterocyclic ring of the instant invention in view of the level of skill in the art taught by Bedell et al. Therefore the instant invention is not taught or fairly suggested by Ellsworth et al. in view of Bedell et al. and further in view of Shell.

The closest art is Imamura et al. (WIPO Publication WO2004/080990, published 23 Sep 2004, of record) in view of Shell (US Patent 5,582,837, issued 10 Dec 1996, of record).

Imamura et al. in view of Shell teaches as detailed in the Office Action mailed 27 Feb 2008.

In the instant application foreign priority is perfected by filing of an English language translation of foreign priority document JAPAN 2004-61429, which provides support for the instant claims with a foreign priority date of 04 Mar 2004. Therefore WIPO Publication WO2004/080990, published 23 Sep 2004 in Japanese, is not prior art under 35 U.S.C. 102(a) or (e). The instant invention is not taught or fairly suggested by Shell alone.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably

Art Unit: 1623

accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Claims 1, 3, 5-10, 12, 13, 15-20 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1623

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jonathan Lau
Patent Examiner
Art Unit 1623

/Shaojia Anna Jiang/
Supervisory Patent Examiner
Art Unit 1623